

FARICIMAB VS STANDARD OF CARE IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION AND DIABETIC MACULAR EDEMA: A COST-UTILITY ANALYSIS IN ITALY

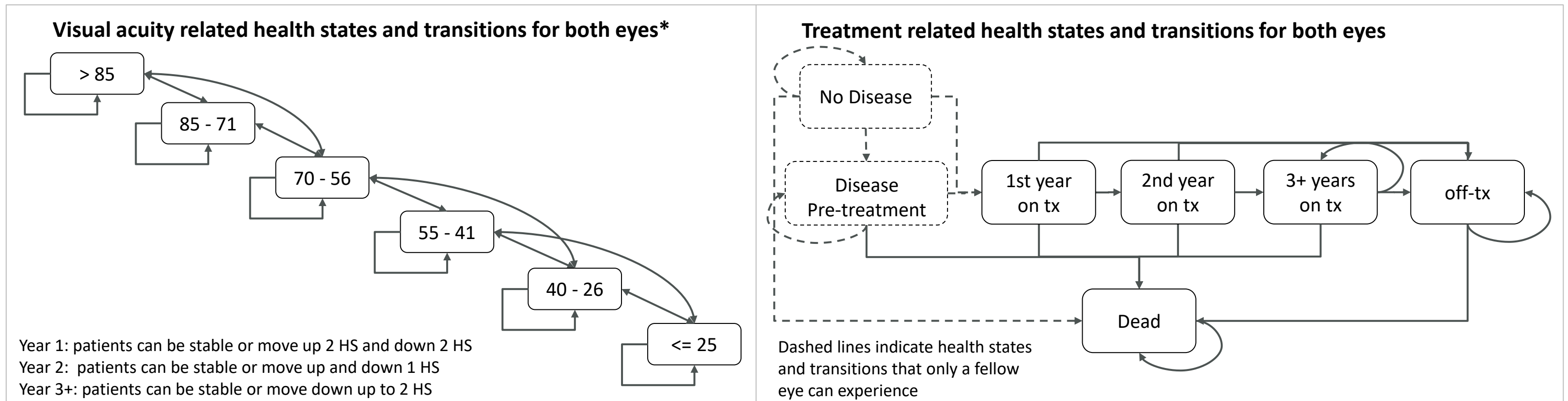
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Objective

- Neovascular Age-Related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME) rank among the leading five causes of vision loss [1].
- Current Standard of Care (SoC) for these conditions involves anti-Vascular Endothelial Growth Factor (anti-VEGF) therapies. While they have significantly reduced the rates of vision loss, their need for regular and frequent injections can lead to under-treatment and sub-optimal outcomes [2,3].
- Faricimab is the first bispecific antibody designed for the eye. This novel therapy, administered with intervals of up to 16 weeks, demonstrated its potential to meaningfully extend the time between treatments with sustained efficacy, thereby reducing the overall treatment burden [4,5].
- This study aims to assess the cost-utility of faricimab vs. SoC in patients with nAMD and DME, from both the perspective of the Italian National Health Service (SSN) and Society.

Methods

- Two 28-day cycles Markov models were adapted to the Italian context to estimate lifetime clinical outcomes and costs of patients receiving either faricimab or SoC.
- On-label, anti-VEGF therapies in Italy, were considered for this analysis.
- In line with faricimab non-inferiority Clinical Trials (CTs) results [4,5] and Note 98 report [6], treatments were assumed to have similar risk/benefit profile.
- Health-state occupancy and treatment discontinuation rates were informed by CTs and held constant after the second year [7]. For patients who discontinued treatment, the transition to another therapy was not considered.
- Injection frequency was derived from Tenaya/Lucerne - Yosemite/Rhine CT results (faricimab and aflibercept) [4,5]. Summary of product characteristics (SmPC) and Note 98 report were used for the remaining alternatives [6].
- SoC injection frequency and relative price were defined as the weighted average of on-label anti-VEGFs according to National Observatory on the Use of Medicines (OsMed) 2020 consumption report [8].
- General population mortality rates were adjusted to account for increased mortality in patients with visual disabilities, in line with NICE analyses [7,9].
- Health state utilities, based on the VA level of both eyes, were derived from a published regression model [10]. Consistent with NICE guidelines, the disutility associated with intravitreal injection discomfort was also considered [7,11].
- Direct costs included drug acquisition and administration, while indirect costs comprised the cost of lost productivity of patients and caregivers. Unit costs were retrieved from published literature [11] and Italian sources [12] (*Table 2*).
- A lifetime horizon (25 years) was considered. Costs and health gains were discounted at an annual 3% rate.

Figure 1 – Model scheme

Patients enter the model based on the initial visual acuity (VA). VA-level distribution was derived from faricimab clinical trials. To model the clinical progression observed in patients with DME and nAMD, three time periods were considered: (i) year 1, the induction phase during which most of the visual improvements occur; (ii) year 2, defined by disease stabilization and maintenance of previously achieved visual improvements; (iii) year 3+, characterized by the possibility of reducing treatment intensity and long-term maintenance. Treatment efficacy varies based on baseline VA in the first year. Subsequently, the transition probabilities no longer depend on the VA.

*7.3% of nAMD patients and 46.5% of DME patients were assumed to have both eyes affected, with respective second-eye development incidences of 1.4% and 0.8% per model cycle [7,9].

Table 2 – Unit costs

Cost category	Cost item	Value (€)
Direct costs	Faricimab*	631.92
	Aflibercept*	667.85
	Ranibizumab*	669.66
	Brolucizumab*	613.70
	SOC** nAMD	667.47
	DME	668.56
	IVT administration	247.20
Indirect costs	Optical coherence tomography	37.10
	Productivity loss/IVT injection day	159.00

Resource consumption

The cost of IVT injection comprised both the administration and the optical coherence tomography costs, with data sourced from the literature [11].

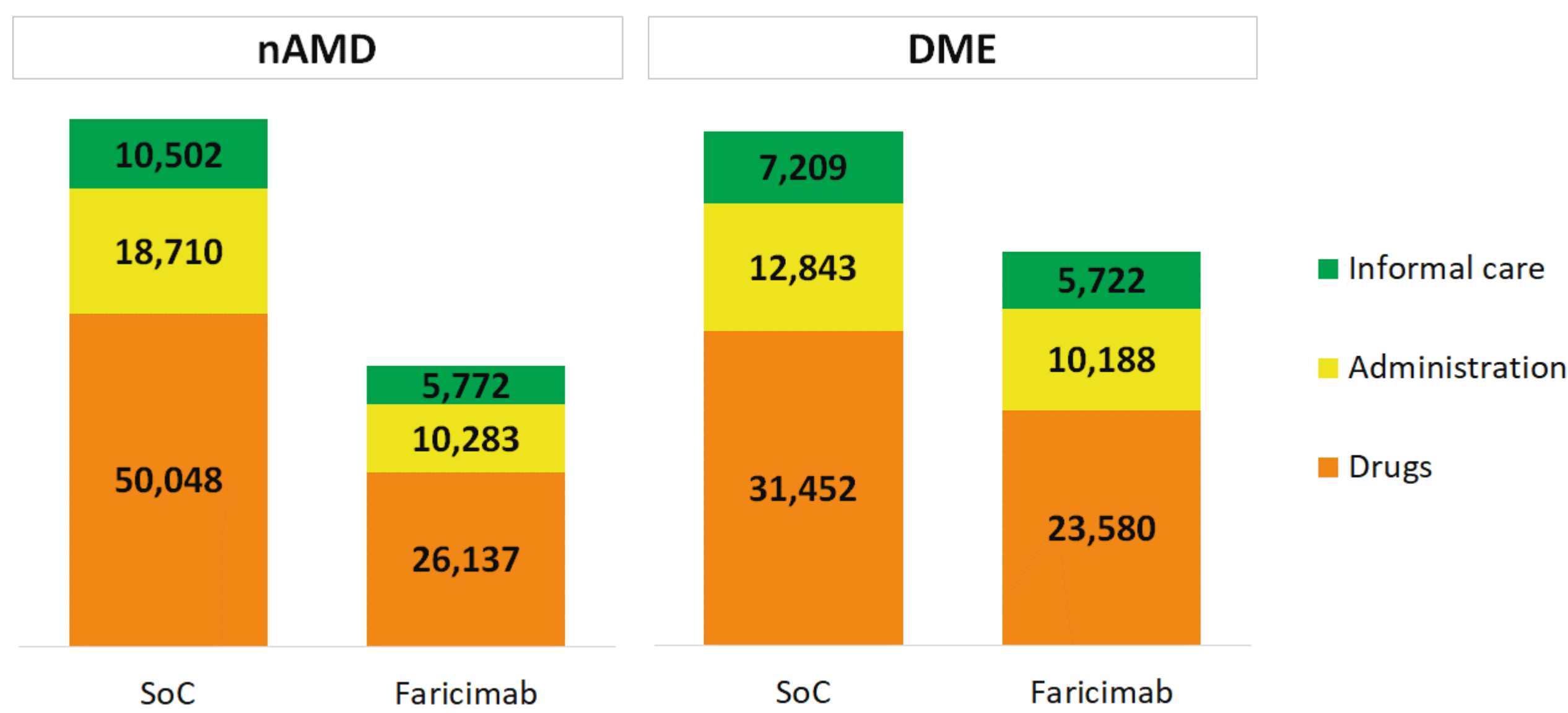
Productivity loss

The cost associated with productivity loss for patients and caregivers was estimated based on the mean number of hours required for administration (€14 per hour for an average of 6 hours per injection). It was assumed that 90% of patients were accompanied by a caregiver [13].

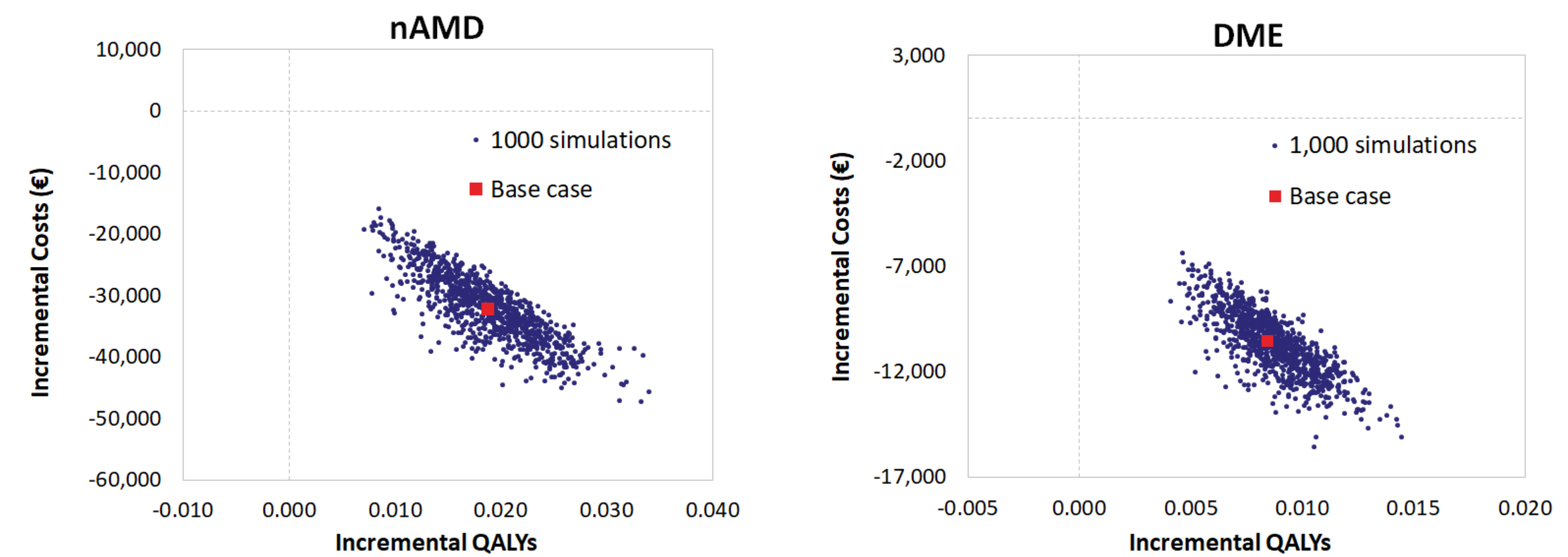
* Ex-factory price net of mandatory discounts. ** Injection frequency and price defined as on-label anti-VEGFs weighted average according to OsMed consumption distribution.

Results

- Faricimab demonstrated **greater efficiency** compared to SoC (5.37 vs 5.35 QALYs for nAMD and 8.72 vs 8.71 QALYs for DME), due to the **reduced frequency of intravitreal administrations** (*Table 3*).
- Considering the SSN perspective, faricimab was associated with **lower costs** compared to SoC, with a total savings of €-32,338 for nAMD and €-10,527 for DME. From a societal perspective, savings were even more substantial, amounting to €-37,068 and €-12,015, respectively (*Table 3* and *Figure 2*).
- Faricimab remains dominant vs. SoC up to a reduction of the comparators price of 64% for nAMD and 33% for DME.
- PSA results confirm the main analysis, with all simulations falling within the **dominance** region of the cost-effectiveness plane (*Figure 3* for SSN perspective).

Figure 2 – Cost breakdown (€).*Table 3 – Summary benefits of faricimab: reduced costs and an improved quality of life (costs in €)*

Comparator	Disease	Δ QALY	Δ Direct costs	Δ Indirect costs
Aflibercept	nAMD	0.011	- 19,960	- 2,833
	DME	0.006	- 7,787	- 1,046
Brolucizumab	nAMD	0.005	- 7,548	- 1,360
	DME	-	-	-
Ranibizumab	nAMD	0.031	- 52,334	- 7,773
	DME	0.012	- 14,814	- 2,177
SoC	nAMD	0.019	- 32,338	- 4,730
	DME	0.008	- 10,527	- 1,487

Figure 3 – Incremental cost-effectiveness plan (SSN perspective)

Conclusions

Faricimab was the **dominant strategy** compared to SoC in the treatment of both nAMD and DME, generating significant economic benefits, particularly from the societal standpoint.

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